HIV/AIDS Section Workgroup on ADAP
Meeting Summary
December 14, 2016

Roll Call
Present: Paul Arons, Steven Badura, Jeff Beal, Martha Buffington, Annie Farlin, Earl Hunt, Leonard Jones, Marcia King, Jimmy Llaque, Joe May, Paul McKeel, Kim Molnar, Michelle Scavnicky, James Talley, Debbie Taylor, Bonnie Tiemann, Matthew Tochtenhagen, Lorraine Wells, and Suzanne Williams.

Absent: Sandy Arts, Carol Broxton, Jose Castro, Christine Collis, Karen Creary, Tammy Cuyler, Michael D'amico, Lorenza Haines, Kamaria Laffrey, Elizabeth Sherman, and Gregory Timmer.

Welcome
Dr. Beal announced that Annie Farlin has moved to another role within the HIV/AIDS Section but would continue to provide support to the Workgroup until someone else is hired to fill her role.

Approval of September 21, 2016 Meeting Minutes
Leonard Jones made a motion to approve the minutes from September 21, 2016 and Marcia King seconded. **Minutes unanimously approved.**

<u>Old Business</u>
Addition of Medication to the ADAP Formulary
An email was sent to workgroup members on October 27, 2016 to vote on reinitiating the 2010 ADAP formulary.
Members unanimously approved (14 votes).
The request will now go to the Pharmacy and Therapeutics Committee of the Florida Department of Health Pharmacy. The goal is to have the change in place in the Provide Enterprise (PE) system by the Spring 2017.

Adding Vaccines to the formulary
At the end of the last call (September 21, 2016) there was no resolution on whether or not to add the flu vaccine as part of the formulary in time for the upcoming flu season. The workgroup is being asked to look not only at the flu vaccine but all other HIV-related vaccines.

Discussion:
- In the previous formulary hepatitis A and B were included as part of the formulary. The flu vaccine has not.
- Dr. Arons proposed that the formulary include flu medications as well as the vaccine and asked if Tamiflu® had been covered in the previous formulary. Debbie Taylor reported that Pneumovax® and Tamiflu® were on the prior formulary. Since the group has already agreed to reinitiate the 2010 formulary, those vaccines would be covered.

- Dr. Beal mentioned that the 09 Program offers the hepatitis A & B vaccines, pneumococcal, and influenza but there are limited supplies of money and when they run out other programs are required to pick up the costs (Part B). Adding them to the ADAP formulary would help alleviate some of the burden to the 09 Program**.**
- Human papillomavirus (HPV) vaccine is not on the 2010 formulary so adding that would be helpful. Eligibility would be based on the recommendations of the Immunizations Advisory Committee which for HPV is either 26 or 27.
- Prevnar 13® should be included as a recommendation.
- Jimmy Llaque indicated that phase II of the ADAP formulary expansion would include other drug classes and vaccines would be included in that.

Martha Buffington made the recommendation that the workgroup review all of the immunizations recommended by the Immunizations Advisory Committee and request that ADAP add them to the formulary and Leonard Jones seconded the motion. **Motion unanimously approved.**

Hydroxyurea
Hydroxyurea is no longer recommended for use with any antiretroviral (ARV) regimen. Should that be excluded when the formulary reverts back to the 2010 formulary.
Martha Buffington motioned to remove hydroxyurea from the ADAP formulary and James Talley seconded the motion.
Motion unanimously approved.

Is Hepatitis status part of Provide Enterprise (PE) system?
Dr. Beal provided a framework for the discussion to include whether or not the hepatitis B & C status should be self-reported by the patient or if there should be documented labs to support the reported status.

Jimmy Llaque reported that since the last call they have spoken to the developer of PE system about this and hepatitis status is not included. The first priority with the PE is to eliminate unnecessary steps in the eligibility and enrollment process. The preference is to automate a data extract from other systems where this information is already being recorded and make it available through PE. A number of steps need to take place first in order for that to take place so the response will not be immediate.

Dr. Arons expressed concern that hepatitis status impacts ARV therapy greatly and providers need to know this information. Also, that ADAP is committed to treating patients who are co-infected with HIV and hepatitis so it is urgent to have this issue on a fast-track for review.

Q: How soon can we have something in place so that we reliably know the viral hepatitis status of all the people that are receiving ADAP services?

A: Jimmy Llaque reported that not all information would transfer over because it is currently being housed in other systems such as surveillance and eHARS. ADAP staff

will try to make the information that would be available through the data transfer available in the first quarter of 2017.

Dr. Arons wants to elevate this particular issue as the highest priority. Bonnie Tiemann agreed that it needs to be included in PE as soon as possible.

Dr. Beal suggested the following:

- That the group request a data punch as a test to determine how difficult it is to extract the data and also check for completeness.
- Start a subgroup to discuss how we can gather this information. Need to include ADAP field staff and ADAP central office staff to this workgroup as their knowledge is invaluable.

The goal would be to let ADAP clients know that there is treatment available and to make them aware of why we want them to know their hepatitis status. It might not be inappropriate to have ADAP field staff asking clients if they know their status and if not, advise them to find out and report at their next drug pick-up date.

Jimmy Llaque stated that he was not aware of any other ADAP program nationwide that has hepatitis status as a requirement for program qualification.

The topic was tabled and will be discussed further on an upcoming call to determine whether or not a subgroup is appropriate.

- Leonard Jones agreed to look at the data that is currently being collected. He will report back to the group on the next call.
- Debbie Taylor will check to see what is being captured in the HMS system when patients are assessed.

Please email any thoughts or suggestions on this topic to debbie.taylor@flhealth.gov.

Legal Status of Medications for Test & Treat Program

- Attorney from the Department of Health (DOH) interprets the protocol to require that an individual must be treated in a county health department (CHD) with a CHD medical record maintained.
- Laura Reeves and Jeff Beal met with a PharmD at HRSA who is responsible for providing guidance on the 340b Program. They were provided with some suggestions on how to possibly expand outside the CHDs.
    - Dr. Beal and Laura to meet with the with the DOH attorneys to see if any of these suggestions will work.
    - An alternative would be to contract for services with CBOs allowing community-based organizations (CBOs) who have 340b pricing to provide test and treat services.
    - Jimmy Llaque will look into the possibility of using a voucher system.

Standards of Care – Update
The HIV/AIDS Section was told that they were required to have written formal standardized guidelines on care. In the past the Department of Health and Human Services (DHHS) guidelines, American Association for the Study of Liver Diseases (AASLD), etc. could be used as the standard by which the Part B Program could be audited. The Part C programs are now required to create a standard of care guidelines based on the interpretation of the various guidelines referenced.

Dr. Beal met with the Part B Project Officer and explained why standards of care should be based on current recognized guidelines. A subcommittee has been formed to develop an evaluation template to monitor compliance with these guidelines in Lead Agencies throughout Florida.

Debbie Taylor sent out a draft of the Standards of Care document with comments due back on December 8, 2016. Edits will be made and the revised document will be shared with the group.

Any additional edits should be sent to Debbie Taylor at debbie.taylor@flhealth.gov.

New Business
Patient Care Update (Joe May)
The State of Florida Patient Needs Assessment is underway.

- Available in three languages: Creole, Spanish, and English
- The survey will remain open until January 3, 2017.
- There have only been only 1,500 surveys completed.
    - Patients are survey weary
- The website for the survey is floridaneeds.org

Update on the Corrective Action Plan for HRSA
Patient care is currently updating the plan for submission to HRSA in January 2017. Joe May will provide a more detailed update on the next call.

CQM Update (Lorraine Wells)
Lorraine Wells gave a presentation on the Department of Health's Clinical Quality Management (CQM) Program.

All quality management (QM) programs must have three major components

- Developing an Infrastructure
- Performance Measures
- Quality Improvement Initiatives

Developing an Infrastructure

- Establish a CQM Statewide Executive Committee
    - Utilizing the existing senior management infrastructure
        - Responsible for setting goals
        - Establishing targets to achieve the goals

    - Review and approve statewide quality improvement (QI) initiatives
    - Review program indicators bi-annually to assure progress towards specific goals and objective are met
- CQM activities have been added to job descriptions of staff positions through the HIV/AIDS Section.
- HRSA's CQM requires that all sub recipients have a documented and approved CQM Plan.
    - Laura Reeves and Lorraine Wells conducted a webinar on November 22, 2016 for all lead agencies to provide clarity on what was needed.
    - Plans were due by December 1, 2016. They are currently being reviewed to ensure that they are operational and meet the requirements outlined in the HRSA guidance. Final plans are due by March 2017.
- Develop a plan that defines our goals and objectives (Integrated Plan)
- Develop performance measures and use data to measure progress and make improvements to our stated goals
- Develop standards of care that are consistent with the Public Health Service guidelines
- Ensure that there is participation from our stakeholders, sub recipients, stakeholders, and other Ryan White partners

Performance Measures

- Part B is required to set the performance measures for each service category regardless of whether or not they are provided in the state.
    - For those that are services that are highly utilized two or more measures are required. All others are required to have at least one
    - Used data to inform the process: looking at client utilization information and funding allocation/expenditures to determine which services were high utility
    - 10 services had high utility; 9 services had low utility
- The HIV/AIDS Section recently established performance measures for all 19 funded service categories
- Defining how the infrastructure will work and the platform in which the CQM will run
- Performance measures have been drafted and upon approval will be shared with the Florida Comprehensive Planning Network (FCPN) for the sake of knowledge and participation.

Quality Improvement (QI) Initiatives

- Standardization of Services for Patient Care (SOS)
    - A need to clearly define and align patient care services outlined in the administrative guidelines with HRSA's allowable uses for funds
    - Will be putting team together from headquarters as well as the FCPN
    - Will address LPAP and Emergency Financial Assistance (EFA)
        - The work that this group does through the expansion of the ADAP Formulary will help in this regard
    - Currently putting together patient care annual goals

ADAP Program Update (Jimmy Llaque)
Jimmy Llaque asked the group to present quality improvement recommendations that they feel would help strengthen the ADAP Program.

Policy & Procedure Manual
Steven Badura, ADAP Operations Manager, distributed a copy of the updated manual on July 1, 2016. Minor revisions were made and a new manual is scheduled for release in January 2017. There were no major policy changes.
The updates to the manual mainly consist of:

- Clarifications on frequently referenced issues that have come up with the implementation of the new Provide system
- Clarifications on language in the new manual (e.g. closure vs. suspension).
- Details on additional reports available in the new system
- Information on the Premium Tax Credit
    - Eligibility and effect on clients in terms of marketplace transition.

Update on the Provide Enterprise (PE) System Implementation
The old database system used to capture client files was replaced by the Provide Enterprise (PE) System on September 1, 2016. All of the data in the old system was transferred into the new system.

The new system will be used to:

- Bring clients into ADAP
- Create new client records
- Automatically identify incomplete data
- Flag inappropriate entries
- Process information to enroll or reenroll clients and identify which specific services they are eligible to receive (e.g. direct medication dispensing, insurance, premium and co-pay assistance, etc.)
- Capture complete information for each client (e.g. financial, lab reports, prescriptions, etc.)
- Monitor clients' medication pick-up

Update on Marketplace Open Enrollment Activities
On October 24, 2016 there were 167 plans in Florida. Those plans were reviewed and 33 plans, with varied availability by county, were identified. Information on those plans was released on November 8, 2016.

Previously the program assisted clients from 100-250% of the federal poverty level (FPL). This year it was expanded up to 400% of the FPL. The program was opened to new clients as well as those that were returning. Anybody involved in a COBRA plan would also qualify.

In previous years the enrollment was managed centrally. With the new system, more access has been given to the local counties.

There continue to be challenges:

- People are automatically being reenrolled. Sometimes to a plan that may not be in the best interest of the client or the program.
- Some clients who had United Healthcare in 2016 who no longer have that option in 2017.
- Florida Blue changed their pharmacy networks

The program has made some changes to help facilitate enrollment this year:

- Added three data entry staff in the Central Office.
- Had series of calls with the remaining carriers to ensure that all the data points are being captured and the payments are being made in a timely fashion.
- Reached out to the Office of Insurance Regulation to work on contacts with the other carriers.
- Initiated enrollment tracking records within the PE system which allows for the tracking of clients from one year to the next.

There is a goal to enroll 1,700 new clients into the marketplace for 2017

Q: How many clients will be enrolled in ADAP? How many of those will have their drugs covered by insurance other than ADAP directly?
A: At the beginning of this year there were about 2,500 clients receiving assistance with their premiums in the marketplace. Depending on how many new clients we can move into the marketplace that number could go up by an additional 1,500-1,700 clients. We could potentially be reaching between 3,500-4,000 clients enrolled in the marketplace by the start of next year. There were 18,000-19,000 clients enrolled in ADAP throughout the year. 1 out of 4 clients have assistance with insurance premiums or co-pays through ADAP, so about 25% of the total enrollment.

Hepatitis C Medications – review and vote
There is a recommendation to add three hepatitis C treatment drugs to the ADAP formulary. Jimmy Llaque has assured that the drugs could be added to the formulary.

Current enrollment with Hep C tx program through ADAP:

- 57 patients enrolled.
- 15 currently in treatment and 14 who have not started treatment yet

The recommendation is to expand the formulary to include:
Zepatier™ (manufactured by Merck for genotypes 1 & 4). A single tablet once a day. 12 week course of treatment
Technivie™ (manufactured by AbbVie for genotype 4) This is a version of Viekira Pak® which is already on the formulary. Instead of three components it has only two.
Daklinza™ (manufactured by Bristol-Meyers Squibb for Genotype 3) This drug is approved for use in combination with sofosbuvir. This drug becomes more expensive because it has to be combined with another drug. About 10% of hepatitis C infections are genotype 3.

Marcia King made the motion to include Zepatier™, Technivie™, and Daklinza™ to the ADAP formulary and Martha Buffington seconded the motion.
Motion unanimously approved.

Member Comments:
Martha Buffington made a request to add Alinia (used to treat Crypotosporidium parvum) to the formulary. Dr. Beal indicated that the request would be researched and be a part of a future discussion by the workgroup.

No further business to discuss, the meeting ended at 4:45PM (EST).